

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Howard SANDS, et al.

Serial Number: 10/698,983

Filing Date: October 31, 2003

Title: PHARMACEUTICAL FORMULATIONS
TARGETING SPECIFIC REGIONS OF
THE GASTROINTESTINAL TRACT

Group Art Unit: 1615

Examiner: Carlos A. Azpuru

CONFIRMATION NO: 8849

ELECTRONICALLY FILED ON: January 11, 2006.

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted, if required, pursuant to 37 C.F.R. §§1.97-1.98, as indicated below.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

☒ 37 CFR §1.97(b). This Information Disclosure Statement should be considered by the Office because:

- ☐ (1) It is being filed within 3 months of the application filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
- ☐ (2) It is being filed within 3 months of entry of a national stage as set forth in §1.491 in an international application;
-- OR --
- ☒ (3) It is being filed before the mailing date of the first Office Action on the merits;
-- OR --
- ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under §1.114.

☐ 37 CFR §1.97(c). Although this Information Disclosure Statement is being filed after the period specified in 37 CFR §1.97(b), above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:

- ☐ a certification as specified in §1.97(e) provided concurrently herewith;
-- OR --
- ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.

☐ 37 CFR §1.97(d). Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:

- A. a certification as specified in §1.97(e); and
- B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.

☐ 37 CFR §1.97(e). A certification signed by an Attorney of Record is provided herewith as required under 37 CFR §§1.97(b) and (c).

☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

- ☐ Copies of each of the references listed on the attached Form PTO/SB/08A are enclosed herewith.
-- OR --
- ☐ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08A are NOT enclosed.
-- AND/OR --
- ☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08B are enclosed in accordance with 37 CFR §1.98(a)(2).
-- AND/OR --
- ☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

- ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.
- ☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation of the non-English language reference(s) is provided herewith.
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR §1.97(e)(1).
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636-304.201).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI



By: _____

Shirley Chen, Reg. No. 44,608

Dated: January 11, 2006 _____

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known		
				Application Number		10/698,983
				Filing Date		October 31, 2003
				First Named Inventor		Howard Sands
				Art Unit		1615
Examiner Name		Carlos A. Azpuru				
Sheet	1	of	1	Attorney Docket Number		12636-304.201

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		BROWN, R. et al. Demethylation of DNA by decitabine in cancer chemotherapy. <i>Expert Rev Anticancer Ther.</i> 2004; 4(4): 501-510.	
		GILBERT, J. et al. The Clinical Application of Targeting Cancer through Histone Acetylation and Hypomethylation. <i>Clinical Cancer Research.</i> 2004; 10: 4589-4596.	
		HERMAN, J. G. et al. Gene Silencing in Cancer in Association with Promoter Hypermethylation. <i>The New England Journal of Medicine.</i> 2003; 349(21): 2042-2054.	
		LEONE, G. et al. DNA methylation and demethylating drugs in myelodysplastic syndromes and secondary leukemias. <i>Haematologica.</i> 2002; 87(12): 1324-1341.	
		LEONE, G. et al. Inhibitors of DNA methylation in the treatment of hematological malignancies and MDS. <i>Clin Immunol.</i> 2003; 109(1): 89-102.	

Examiner signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.